

## REMARKS

### Double-patenting rejection

Claims 1-26 continue to stand rejected on the basis of obviousness type double-patenting. Applicant requests withdrawal of this rejection on the basis of the terminal disclaimer filed in response to the previous office action.

### Section 112 rejection of claim 2

Applicant proposes amending claim 2 to explicitly define a physical volume. The proposed amendment to claim 2 removes the basis for the section 112 rejection.

### Section 103 rejection of claim 2

For an understanding of claim 2, Applicant draws attention to the discussion of equivalent volume beginning with the second full paragraph on page 7 of the specification.

In rejecting claim 2 as being obvious in view of *Nadol*, the Examiner suggests that *Nadol* teaches a balloon having a 70% equivalent volume. It is unclear to Applicant how the Examiner so readily reaches this conclusion. Applicant's experience has been that it is difficult to ascertain equivalent volume of a balloon without experimentation. Applicant requests that the Examiner share his special insight into how to determine equivalent volume of a balloon by merely inspecting the data provided by *Nadol*.

### Section 102 rejection relying on *Nadol*

Claims 1, 21, and 22 stand rejected as being anticipated by *Nadol*. Presumably, somewhere in *Nadol* lies a teaching of a balloon having an equivalent volume selected to permit the eardrum to respond to incident acoustic waves to an extent that permits the perception of sound. However, the Examiner has not identified any such teaching. Instead, the Examiner states that *Nadol*'s "basic tenet" involves providing pliant balloons for acoustic transmission.

Almost by definition, any prior art reference would have the same "basic tenet" as the application under examination. Indeed, were the patent law consistent with the Examiner's position, the very existence of *Nadol* would foreclose the patenting of any further improvement in middle-ear balloon implants.

Applicant : Saumil N. Merchant  
Serial No. : 09/625,644  
Filed : July 26, 2000  
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Attorney : Docket No.: 00633-025001

Applicant is not seeking to patent a "tenet." Applicant seeks to patent a structure, the limitations of which are recited in claim 1. A proper rejection under section 102 requires that each limitation of the claim be taught by the reference.

Despite having repeatedly cited *Nadol*, the Examiner has never identified specific passages in *Nadol* that teach the claim limitations. Instead, all the Examiner has done is to observe that Applicant and *Nadol* address the same technical problem. This is insufficient as a matter of law to maintain a rejection under section 102(b).

Applicant draws attention to the attached declaration under 37 CFR 1.1.32 in which the named inventor of the cited reference states that his issued patent does not disclose an embodiment having the structure recited in claim 1.

Since the Examiner has been unable to identify a specific teaching in *Nadol* that discloses the claimed structure, and since Dr. Nadol himself has stated that his issued patent contains no such teaching, Applicant requests reconsideration and withdrawal of the rejection.

Now pending in this application are claims 1-26, of which claims 1, 21, and 22 are independent. Attached is a marked-up version of the changes being made by the current amendment. No additional fees are believed to be due in connection with the filing of this response. However, to the extent fees are due, or if a refund is forthcoming, please adjust our deposit account 06-1050.

Respectfully submitted,

Date: 11/21/03

  
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**Version with markings to show changes made**

**In the claims:**

Claim 2 is amended as follows:

2. **(Twice Amended)** The implant of claim 1, wherein said pliant membrane forms a balloon having a physical volume, said balloon having an acoustic impedance corresponding to an equivalent volume of at least 70% of [~~its~~]said physical volume.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Saumil N. Merchant et al.  
Serial No. : 09/625,644  
Filed : July 26, 2000  
Title : MIDDLE-EAR IMPLANT

Art Unit : 3738  
Examiner : Isabella, D.

Commissioner for Patents  
Washington, D.C. 20231

**RULE 1.132 AFFIDAVIT**

1. I am the named inventor of U.S. Patent No. 5,536,430 (the '430 patent).
2. In the '430 patent, I disclose balloons to be implanted in the middle-ear.
3. The purpose of the balloons disclosed in the '430 patent was to acoustically couple the eardrum to the middle-ear.
4. Following clinical trials, I found that the balloons described in the '430 patent did not significantly enhance acoustic transmission between the eardrum and the middle-ear.
5. I believe that the materials disclosed in the '430 patent, when used to make the balloons disclosed in the '430 patent, resulted in balloons that did not couple sufficient acoustic energy to the middle-ear to enhance a patient's perception of sound.

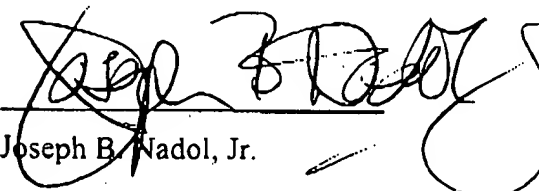
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Respectfully submitted,

  
Joseph B. Nadol, Jr.

JAN. 21, 2003  
Date